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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/040,303      | 10/19/2001  | Nader Pourmand       | SUPP-P01-012        | 9829             |

28120 7590 01/23/2006

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EXAMINER

YANG, NELSON C

|          |              |
|----------|--------------|
| ART UNIT | PAPER NUMBER |
|----------|--------------|

1641

DATE MAILED: 01/23/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                               |                                 |  |
|------------------------------|-------------------------------|---------------------------------|--|
| <b>Office Action Summary</b> | Application No.<br>10/040,303 | Applicant(s)<br>POURMAND ET AL. |  |
|                              | Examiner<br>Nelson Yang       | Art Unit<br>1641                |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 21 October 2005.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-17 and 113-140 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-17 and 113-140 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Response to Amendment***

1. Applicant's amendment of claims 1, 125 is acknowledged and has been entered.
2. Applicant's addition of claims 134-140 is acknowledged and has been entered.
3. Claims 1-9, 11-16, 113-140 are currently pending.

### ***Claim Rejections - 35 USC § 102***

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

5. Claims 1-5, 7-9, 11-16, 113-134, 136, 137 are rejected under 35 U.S.C. 102(e) as being anticipated by Bauer [US 6,322,963].

With respect to claims 1, 113, 125, Bauer teaches a method comprising immobilizing one or more biological or synthetic macromolecules in proximity to an appropriately conductive base member and then measures an emf, current, or other electrical effect induced in said base member as a result of analyte-related changes in fluctuating electrostatic fields associated with the macromolecular binding agents, wherein a change in motional behavior of the binding agent or addition of electrostatic material associated with the analyte causes an increased electromagnetic induction in the base member and thus signals binding of analyte (column 7,

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lines 25-34). The amount of change in the signal above background readings (generated by the immobilized macromolecules in motion) may be correlated to the concentration of analyte present in the sample of interest (column 7, lines 35-40). Bauer further teaches that the system does not require the application of an external electrical signal (column 21, lines 5-10). Voltage measurement can be made by placing an appropriate resistor between electrode leads (column 15, lines 15-16), wherein one electrode could be considered the working electrode and the other the reference electrode.

6. With respect to claims 2-4, the detection a change in motional behavior of the binding agent or addition of electrostatic material associated with the analyte which causes an increased electromagnetic induction in the base (column 7, lines 25-34).

7. With respect to claim 5, the sample is in solution (column 9, lines 1-3).

8. With respect to claims 7-9, 114-121, 126-129, the immobilized molecule can be antibodies (column 1, lines 54-56), DNA (column 2, lines 8-10), enzymes (column 1, lines 34-36).

9. With respect to claims 11-14, voltage measurement can be made by placing an appropriate resistor between electrode leads (column 15, lines 15-16), wherein one electrode could be considered the working electrode and the other the reference electrode. The measurements are made over time (fig. 10-12).

10. With respect to claims 15-16, the measurements can also be current (column 7, lines 25-28), or charge (column 7, lines 10-15). The measurements are made over time (figs. 10-12).

11. With respect to claims 130-133, the waveforms decay in under a second (fig. 10-12).

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12. With respect to claim 134, Bauer further teaches a detection unit for analyzing signals as a function of analyte interaction (column 12, lines 50-65).

13. With respect to claims 136, Bauer teaches the use of semiconductors (column 17, lines 55)

14. With respect to claim 137, the sensor is responsive to fluctuating magnetic fields (column 17, lines 55-60).

15. Claims 1-4, 6, 11-16, 113, 125, 130-136 are rejected under 35 U.S.C. 102(b) as being anticipated by Gupta et al [Gupta et al, YBCO-FET room temperature ammonia sensor, 2000, Sensors and Actuators B 63, 35-41].

With respect to claim 1, 125, Gupta et al teach a sensor FET and a reference FET that constitute a difference amplifier (p.36, col. 1-2). Changes in the gate voltage is due to adsorption (p. 37, col. 1) of gas molecules to Cu-ions located within the YBCO film (p.39, col.2). The signal is related to the amount of gas such as ammonia in the air (figs. 4, 5).

16. With respect to claims 2, 113, changes in the gate voltage is due to adsorption (p. 37, col. 1) of gas molecules to Cu-ions located within the YBCO film (p.39, col.2).

17. With respect to claims 3-4, the signal can be due to ammonia molecules adsorbed to the layers of the YBCO-FET sensor, as well as leaving the layers (to cause a recovery of the signal) (p. 39, col.2).

18. With respect to claim 6, the detection occurs in a gaseous medium (p. 37, col.2).

19. With respect to claims 11-12, the measurement is performed using a sensor FET and a reference FET (p. 37, col.2).

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20. With respect to claims 13-16, the signal is measured as voltage over time (figs. 4, 5)

which is the result of net positive charges on the surface of the sensor due to adsorption (p. 39, col.2), and which can also be measured as a current.

21. With respect to claims 130-133, Gupta et al demonstrates that the waveform decay occurs fairly quickly, occurring within a minute (fig. 3).

22. With respect to claim 134, Gupta et al demonstrates the sensor response to different gases (p.35, col.2, fig. 5).

23. With respect to claim 135, Gupta et al teach a sensor FET and a reference FET that constitute a difference amplifier (p.36, col. 1-2)

24. With respect to claim 136, the sensor using YBCO films which are semiconducting films (p. 37, col.2).

25. Claims 1-3, 5, 7-9, 12-16, 137-140 are rejected under 35 U.S.C. 102(b) as being anticipated by Holm-Kennedy [US 5,466,348].

With respect to claim 1, Holm-Kennedy teaches a method comprising exposing a device to a solution containing a target material with which the binding layer will attach. The resultant change in attachment charge and/or contact potential will alter the device's quiescent state, wherein the induced charge effects may be used with a FET-type sensor transiently (column 5, lines 40-46). Suitable monitoring equipment coupled to the device can detect this change, confirming that the target substance is indeed present, and providing an quantitative measurement and various amplifying means and feedback features may be used to enhance sensitivity and performance (column 5, lines 47-50).

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26. With respect to claims 2-3, the device detects the binding of a target material to a binding layer (column 5, lines 40-46), which would require the movement of the target material to the binding layer.
27. With respect to claim 5, the sample is found in a solution (column 5, lines 40-42).
28. With respect to claims 7-9, the immobilized molecules may be nucleic acids, proteins (column 9, lines 40-46).
29. With respect to claim 12, Holm-Kennedy teaches an array of sensors (column 9, lines 24-26).
30. With respect to claims 13-16, the device detects a change in charge (column 24, lines 55-60), which can be measured as a current or as a voltage.
31. With respect to claims 137-138, Holm-Kennedy further teaches the use of magnetic beads (column 24, lines 19-25).
32. With respect to claims 139-140, the device detects a change in charge (column 24, lines 55-60), which can be measured as a voltage.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

33. Claims 122-124 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bauer [US 6,322,963] in view of Henkens et al [US 6,391,558].

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With respect to claim 122, Bauer teaches the method of detecting a nucleic acid analyte in a sample, as discussed above. Bauer does not teach that the nucleic acid analyte comprises a SNP.

Henkens et al, however, do teach the detection of SNPs and further teach that SNPs are important for mapping and discovering genes associated with common diseases (column 23, lines 20-25), and that SNPs can be used as genetic markers in mapping studies (column 23, lines 5-10). In particular Henkens et al teach that SNPs have many properties that make them a good choice as the primary analytical target for the study of human sequence variation which are particularly important for mapping and discovering genetic factors that are major health threats (column 22, lines 58-65).

Therefore it would have been obvious to detect SNPs using the method of Bauer as suggested by Henkens et al, because Henkens et al teach that SNPs are composed of DNA and the method of Bauer can be used for the detection of DNA. Therefore, by detecting SNPs in the method of Bauer, it would be possible for mapping and discovering genetic factors that are major health threats.

34. With respect to claims 123-124, Bauer further teaches that the amount of change in the signal above background readings (generated by the immobilized macromolecules in motion) may be correlated to the concentration of analyte present in the sample of interest (column 7, lines 35-40), which would allow the method to be used for profiling.

### ***Response to Arguments***

35. Applicant's arguments with respect to claims 1-9, 11-16, 113-140 have been considered but are moot in view of the new ground(s) of rejection.



*Conclusion*

36. No claims are allowed.

37. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

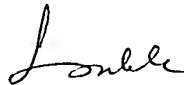
38. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nelson Yang whose telephone number is (571) 272-0826. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (571)272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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39. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Nelson Yang  
Patent Examiner  
Art Unit 1641

  
**LONG V. LE**  
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01/09/06